UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 2666 (JNE/FLN)
This Document Relates to **ALL ACTIONS**	

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT DR. YADIN DAVID

TABLE OF CONTENTS

Plaintiffs rely upon positions and titles that suggest Dr. David has far more regulatory and clinical experience than he actually has, and focus upon how his experience and methodology look, rather than what they mean and how they support his opinions. Dr. David has never outside the context of litigation engaged in the type of regulatory analysis he offers in his report, has virtually no experience in medical device design, and routinely defers to others the very clinical risk assessments Plaintiffs rely upon him to make in this case. The Court should exclude his testimony in full.

I. THE COURT SHOULD REJECT PLAINTIFFS' *IN LIMINE* REQUEST TO EXCLUDE ALL REGULATORY TESTIMONY.

Oddly, Plaintiffs open their response with an *in limine* request seeking to exclude "testimony about the FDA" entirely. (ECF No. 866 at 8-12.) To support this request, Plaintiffs cut-and-paste from their motion to exclude Timothy Ulatowski, in which Plaintiffs challenge his testimony on 510(k) clearance. (ECF No. 756 at 4.). As discussed in Defendants' response to that motion, Mr. Ulatowski's 510(k) opinions are relevant and admissible. (ECF No. 888 at 8-15.) But even if the Court were to disagree, Plaintiffs' arguments and the authority they cite relate only to 510(k) testimony—not to all "testimony about the FDA," which Plaintiffs appear now to want excluded.

As numerous courts have recognized, FDA regulatory opinions—so long as they are made by witnesses with appropriate qualifications using reliable methodologies—are relevant in medical device product liability cases. *See, e.g.*, *Huggins v. Stryker Corp.*, 932 F. Supp. 2d 972, 990 (D. Minn. 2013); *Lillebo v. Zimmer, Inc.*, No. 03-2919, 2005 WL

388598, at *4-5 (D. Minn. Feb. 16, 2005).[1] This is especially true where, as here, the FDA has issued affirmative conclusions touching on the safety of the subject device, based on its own evaluation. (*See* ECF No. 768 at 226, Def. Ex. 4, FDA Safety Alert.)[2]

II. THE COURT SHOULD EXCLUDE DR. DAVID'S REGULATORY OPINIONS.

Dr. David opines on the Bair Hugger's alleged "troubling" regulatory history, contending that its 510(k) submissions misled the FDA and did not demonstrate "substantial equivalence," that it is "adulterated" and "misbranded" under federal law, and that Defendants violated other FDA regulations in its design and development. (David Rpt. (ECF No. 316) at 43-45.) The Court should exclude these opinions entirely.

A. Plaintiffs Do Not Dispute that Dr. David's "Adulteration" and "Misbranding" Opinions Constitute Impermissible Legal Conclusions.

Plaintiffs do not address Defendants' contention that Dr. David's "adulteration" and "misbranding" opinions constitute impermissible legal conclusions, and the Court should exclude these opinions in full. (*See* ECF No. 766 at 8-10.)

---

[1] Plaintiffs ignore passages of their own cited cases that recognize the relevance of regulatory testimony. *See Woodard v. Stryker Corp.*, No. 11-cv-36-F, 2012 WL 3475079, at *9 (D. Wyo. July 16, 2012) ("[T]his testimony is relevant because it will aid the jury in understanding complex federal regulations and assessing . . . compliance"); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1364 (M.D. Ga. 2010) ("A manufacturer's proof of compliance with federal regulations is also a factor to be considered" in a design defect claim).

[2] Plaintiffs' request to exclude all regulatory testimony is ironic given they affirmatively offered a regulatory expert of their own. After FDA's recent statement regarding force-air warming technology, Plaintiffs appear to want to avoid FDA at all costs.

B. Dr. David is Not a Regulatory Expert.

Plaintiffs overstate Dr. David's regulatory qualifications, and rely upon titles that suggest far more experience than he actually has. Examples include:

- **Education.** Plaintiffs claim Dr. David is educated in "medical device regulation" at the "masters and doctorate level." (ECF No. 866 at 13.) In truth, he studied *electrical engineering* and *psychology*. (ECF No. 870 at 56, Pl. Ex. 2, David CV, at 1) Although he testified he took 2 classes touching on "regulatory principles" (Ex. 11, David Dep. at 65:15-22), Plaintiffs do not explain what those classes addressed, or how they qualify Dr. David to reach his opinions.

- **Good Manufacturing Practice ("GMP") Advisory Committee.** Plaintiffs assert "[i]t is preposterous to think" that Dr. David, as chair of the GMP advisory committee, "would be unfamiliar with standards of care in medical device manufacturing practices." (ECF No. 866 at 21.) But Dr. David does not opine on Defendants' manufacturing practices[3]—he speaks to their ***design and marketing*** of the Bair Hugger System, areas he concedes are outside his expertise. (*See* Ex. 11, David Dep. at 189:23-190:2, 191:14-19, 192:10-16, 229:10-14.) In any event, the FDA website demonstrates this committee has not convened—*not even once*—since Dr. David became chair in December 2014,[4] and appears to have convened *only once in the past 20 years*, in a 2013 meeting Dr. David did not attend. (Ex. 12, April 11, 2013 Committee Meeting Roster.)

- **Orthopedics and Rehabilitation Medical Devices Advisory Panel.** Dr. David participated in one meeting of this panel, when he was voted in as a temporary member for an individual session in 1998. (Ex. 13, Excerpts from April 28, 1998 Committee Transcript.)

- **General Hospital and Personal Use Medical Devices Panel.** Dr. David has attended 3 meetings of this panel—none of which occurred in the last ten years. (See Ex. 14, May 4, 2007 Panel Roster; Ex. 15, August 9, 2005 Panel Roster; Ex. 16, Excerpts from September 14, 1998 Committee Transcript.) Furthermore, the publicly stated questions posed to the panel at these meetings asked discrete

[3] Dr. David offers a conclusory opinion in his report that Defendants "failed to meet its obligation for good manufacturing practices under FDA regulations," but otherwise does not discuss, and offers no substantive analysis as to Defendants' manufacturing practices.

[4] *See* GMP Advisory Committee Past Meeting Materials, available at: https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/DeviceGoodManufacturingPracticeAdvisoryCommittee/ucm561204.htm.

scientific questions that did not expressly raise comparison to a predicate device. (*See, e.g.*, Ex. 17, Panel Questions for May 4, 2007; Ex. 18, Draft Panel Questions for August 9, 2005.)[5]

- **Senior Biomedical Research Service ("SBRS") Credentials Reviewer.** The SBRS is a mechanism by which the FDA recruits qualified scientists.[6] Eligibility for this position does not require regulatory expertise. *See* 42 C.F.R. 24.4.

FDA Advisory Committees require members to be scientific experts, not regulatory experts.[7] Panel members are asked to opine on discrete technical questions that may bear upon a regulatory action, but do not require comprehensive regulatory analysis of any device. Accordingly, while Dr. David has consulted for FDA on discrete technical matters in the past, he has never made a substantial equivalence determination, nor has he sat in FDA's shoes to make compliance determinations.

Plaintiffs rely on *Woodard* to argue Dr. David's regulatory opinions are admissible, but the scope of his opinions in that case were much narrower, touching on three issues: that "(1) [defendant] manufactured and marketed a device that was unsafe and presented unreasonable biomedical engineering risk in connection with its use in intra-articular space; (2) [defendant] mislabeled its devices and failed to warn potential

---

[5] Dr. David recalled in general that substantial equivalence questions came up in panel meetings he attended, but recalled no details other than the clinical environment for use of a proctoscope. (Ex. 11, David Dep. at 188:8-189:16.)

[6] *See* "How FDA Promotes and Rewards Our Scientists," available at: https://www.fda.gov/ScienceResearch/ScienceCareerOpportunities/ucm379703.htm.

[7] *See* Advisory Committees: Membership Types, available at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/MembershipTypes/default.htm ("Scientific members of FDA public advisory committees must be technically qualified experts in their field . . . and have experience interpreting complex data. Candidates must be able to analyze detailed scientific data and understand its public health significance.").

end users about the risks resulting from use of this device; [and] (3) [defendant] failed to properly collect and report patient injuries associated with the past use of the device." *Woodard v. Stryker Corp.*, No. 11-cv-36-F, 2012 WL 3475079, at *9 (D. Wyo. July 16, 2012). Dr. David did *not* purport to broadly opine, as he does here, to an allegedly "troubling" regulatory history for the device.

By contrast, in *Stevens*, Dr. David was excluded based upon a report that—much like his report in this case—listed "regulations and conclusions that defendants violated them, along with a narrative of historical facts that does not require an expert to interpret." *Stevens v. Stryker Corp.*, No. 12-cv-63-bbc, 2013 WL 4758948, at *4 (W.D. Wis. Sept. 4, 2013). Plaintiffs wrongly claim the *Stevens* order resulted from "a deficient report, not a deficit of experience." (ECF No. 866 at 12.) As the underlying briefing in that case demonstrates, the very same arguments as to Dr. David's regulatory qualifications were considered by the court. (*See* Ex. 19 at 15-17, Def's Mot. to Excl. Y. David, *Stevens v. Stryker*, No. 3:12-cv-00063-bbc, ECF. No. 117 (W.D. Wis. June 14, 2013) (noting Dr. David's regulatory education consisted of limited classes taken decades ago, that he had never worked for FDA or enforced FDA regulations, and that his regulatory experience was limited to occasional participation on advisory panels); Ex. 20 at 13-14, Pfs.' Mem. in Opp. to Mot. to Excl. Y. David, No. 3:12-cv-00063-bbc, ECF No. 150 (W.D. Wis. July 4, 2013) (contending Dr. David was "abundantly qualified" to offer regulatory opinions because, among other things, he "was appointed to serve as an advisor to the General Hospital Devices committee of the FDA" and "has, since 1994, provided expertise and advice regarding, among other things, approval of 510(k)

applications and adoption of guidance regulations pertaining to medical devices when the FDA has not had the necessary in-house expertise").)

After hearing these arguments, the *Stevens* court "agree[d] with defendants that nothing in David's report suggests that he is a regulatory expert (he is a biomedical engineer). . . ." 2013 WL 4758948, at *4. This Court should do the same.

C. Dr. David May Not Provide a Regulatory Narrative.

Plaintiffs contend Dr. David should be permitted to summarize company documents to the jury (as he does in sections 5 and 7 of his report), to "explain the basis" for his opinions and the "highly technical" information contained in them. But there is nothing "highly technical" about these documents, which consist primarily of company e-mails, letters, and deposition testimony that can easily be understood by a lay jury. (*See* David Rpt. (ECF No. 316) at 19-27, 31-38.) Courts routinely preclude the type of narrative testimony Dr. David intends to give. *In re Rezulin*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004) (rejecting argument that expert's "narrative merely forms the basis for his opinions and helps to explain his reasoning to the jury. . . ."); *see also* ECF No. 766 at 13-14 (listing cases).

III. DR. DAVID IS NOT QUALIFIED TO OPINE ON THE STANDARD OF CARE IN MEDICAL DEVICE DESIGN.

The record is clear that Dr. David has never designed a medical device, and has never even reviewed a Design History File.[8] (Ex. 11, David Dep. at 167:7-12, 201:22-

[8] FDA regulations require manufacturers to maintain a "Design History File" containing "the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of [21 C.F.R. 820]." 21 C.F.R. 820.30(j).

24.) Moreover, Dr. David concedes he lacks any knowledge of industry standards with regard to device design. (*Id.* at 229:10-14.)

Plaintiffs' response exaggerates the import of Dr. David's involvement with the medical device industry, and fails to describe how any of his consulting work gives him knowledge of industry standards in medical device design. For example, Plaintiffs cite to Dr. David's "professional services to manufacturers of medical devices that would like to start or improve their field biomedical service" (ECF No. 866 at 20), which he agreed means "servicing devices in the field." (Ex. 11, David Dep. 63:6-17.) Plaintiffs provide no further specifics about what this work entailed, and it is hard to imagine it gave Dr. David expertise to opine upon device design. *See Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 391 (D. Md. 2001) (expertise in one area "does not *ipso facto* qualify [witness] to testify as an expert in all related areas.").

In the same vein, Dr. David's appointment to the FDA's GMP Committee—a committee that has never convened since his appointment—relates to device *manufacture*, as opposed to *design* and *development*.[9] Plaintiffs provide no reason to think that nominal involvement in this committee qualifies Dr. David to opine on industry standards for designing a medical device.

[9] *See* Charter of the Good Manufacturing Practices Advisory Committee, available at: https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/DeviceGoodManufacturingPracticeAdvisoryCommittee/ucm174948.htm.

IV. THE COURT SHOULD EXCLUDE DR. DAVID'S HAZARD ANALYSIS AND RELATED OPINIONS.

Employing a method of his own design, Dr. David performed a "hazard analysis" of the Bair Hugger, theorizing as to mechanisms by which the device may could feasibly increase infection risk, and concluding that "the device more likely than not contributes to infections." (David Rpt. (ECF No. 316) at 7-8.) The Court should exclude these opinions entirely.

A. Dr. David is Not Qualified to Assess Clinical Risk.

Plaintiffs argue that biomedical engineers are categorically qualified to opine upon clinical risk (ECF No. 866 at 12-16), and cite *Taylor v. Danek*, No. CIV. A. 95-7232, 1999 WL 310647, at *4 (E.D. Pa. May 10, 1999), a case in which a transferor court applied an MDL *Daubert* ruling. Far more instructive, however, is the underlying MDL Court order, which clarified that an orthopedic bioengineering expert could opine upon "how pedicle screws function in the human body and how the human body functionally, ***but not medically***, responds to pedicle screws." *In re Orthopedic Bone Screw Litig.*, No. MDL 1014, 1997 WL 39583, at *3 (E.D. Pa. Jan. 23, 1997) (emphasis added). Here, even assuming Dr. David's biomedical engineering background could qualify him to explain how the Bair Hugger functions, his opinion that "the devices are more likely than not contributing to infections" (David Rpt. (ECF No. 316) at 1, 8) "touch[es] upon subjects in respect to which he is not qualified," *In re Orthopedic Bone Screw*, 1997 WL 39583, at *2, including microbiology, aerobiology, epidemiology, biostatistics, and infectious disease (Ex. 11, David Dep., at 51:19-21; 244:20-22; 245:22-246:3; 284:7-17).

Plaintiffs assert that Dr. David performs clinical risk assessments of devices all the time, but his deposition testimony establishes otherwise—that he has to "rely on physicians and nurses to provide [him] with information about clinical risks and benefits." (Ex. 11, David Dep. at 309:3-7.) Here, he consulted nobody in forming his clinical risk opinions. (*Id.* at 308:19-309:2.)

When pressed about his opinions and methodology in deposition, Dr. David disclaimed that he was making a clinical risk assessment at all:

> Q. Did you make any investigation related to evaluating the potential infection reduction that could result from the use of forced-air warming?
>
> A. I believe you're asking me a clinical question that was not my objective. . . . What I mean by that is simply that my charge was to look at the Bair Hugger 750 from hazard and risk control issues, not from clinical outcomes, the type of question you have for me.

(*Id.* at 278:14-279:5.) Dr. David made similar disclaimers elsewhere during his deposition. (*Id.* at 111:16-112:2, 277:6-11, 279:7-15, 281:10-14.)

In addition, Plaintiffs do not explain how a "hazard analysis" methodology used for hospital purchasing decisions can reliably establish causation for purposes of a product liability lawsuit. Undoubtedly, hospital purchasing decisions require considerations different from those involved in medical causation inquiries, and may result in conservative judgments, based on developing science and in the name of public health and risk mitigation. In contrast, "the courtroom is not the place for scientific guesswork, even of the most inspired sort. Law lags science; it does not lead it." *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 431 (S.D.N.Y. 2016). Plaintiffs have not established Dr. David performs analyses sufficiently rigorous to establish

medical causation under the Rule 702, nor have they established his analysis in this case meets this standard.

B. Dr. David's Hazard Analysis Methodology Is Unreliable.

Plaintiffs' primary defense of Dr. David's methodology is that a deficient underlying basis for an opinion is material only for cross examination. (ECF No. 866 at 25.) To the contrary, the 2000 amendments to Rule 702 require that expert opinions be based upon "sufficient facts or data." Fed. R. Evid. 702, advisory committee's note to 2000 amendment ("[A]n analysis of the sufficiency of the expert's basis cannot be divorced from the ultimate reliability of the expert's opinion."). Substantial case law since then recognizes that expert opinions based upon biased subsets of materials, selective literature reviews, and a lack of testing are unreliable and therefore inadmissible. (*See* ECF No. 766 at 23.)

Plaintiffs admit Dr. David applied his *own* risk assessment methodology, rather than the ISO 14971 standard used by both the medical device industry and FDA.[10] (*See* ECF No. 866 at 29.) Although they argue his methodology generally aligns with ISO 14971, they compare only the titles of each step, and ignore the details. (*Id.* at 30-31.) For example, ISO 14971 does not merely instruct a user to "estimat[e] the risk(s) for each hazardous situation," but also provides an entire page of methodology that is nowhere to be found in Dr. David's report. (*See* Ex. 21, ISO 14971 standard, § 4.4 (2007).) Plaintiffs do not demonstrate this methodology was followed.

[10] *See* "Recognized Consensus Standard No. 5-70," available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=33989 (recognizing ISO 14971 as the "complete standard").

Moreover, Dr. David's deposition testimony makes clear that his methodology was adapted from MITRE, which Dr. David uses in the context of disaster preparedness, not medical device manufacture. (Ex. 11, David Dep. at 169:23-170:22.) This litigation requires no analysis of how a Bair Hugger will function amid a disaster, so Dr. David's methodology does not fit the opinions he purports to reach.

Finally, Plaintiffs contend Dr. David based his hazard analysis opinions on a review of an "extensive body of literature, documents, testimony, expert testing, as well as inspection of the device itself." (*See* ECF No. 866 at 5.) The record reveals otherwise.

Literature Review. Plaintiffs do not dispute Dr. David ignored relevant but unfavorable literature, and instead assert (without support) that Dr. David considered studies "frequently touted" by Defendants. Contrary to Plaintiffs' claims, Dr. David's literature review did not list *any studies* concluding that the Bair Hugger does not increase infection risk. (David Rpt. (ECF No. 316) at 27-31.) A reliable literature review would have identified the "publically available medical literature" relied upon by the FDA when it concluded that forced air warming devices actually *decrease* infection risk. (ECF No. 768 at 226, Def. Ex. 4, FDA Safety Alert.)

Documents, Testimony, and Expert Testing. Plaintiffs do not dispute Dr. David reviewed only a small fraction of the material reviewed by Mr. Ulatowski, or that it was primarily counsel-selected. (ECF No. 866 at 32-33.) Plaintiffs further concede Dr. David performed no substantive testing of his own, and while they contend he relied upon testing that was performed by Defendants, they do not identify any such testing that supports Dr. David's conclusions. (ECF No. 866 at 26, 34.)

Inspection of the Device. Plaintiffs admit Dr. David's device examination contributed nothing to his substantive analysis. (ECF No. 866 at 25-27.)

For all of these reasons, Dr. David's "hazard analysis" opinions were not derived from a reliable methodology, and lack foundational reliability.

V. THE COURT SHOULD EXCLUDE DR. DAVID'S ALTERNATIVE DESIGN OPINIONS.

The Court has already ruled that conductive heating technologies are not feasible alternative designs to the Bair Hugger (which uses convective heating); and has rejected the arguments Plaintiffs now reassert. (ECF No. 249 at 2.) Plaintiffs offer nothing new to warrant reconsideration of that prior order.[11] Accordingly, the Court should exclude any opinion that conductive devices like the VitaHeat UB3 and Berchtold Tablegard are feasible alternative designs.

Moreover, contrary to Plaintiffs' contention, the modification of warning information does not make an "alternative design" for purposes of design defect. *See* Restatement (Third) of Torts: Prod. Liab. § 2 cmt. n. (1998) ("Design and failure-to-warn claims . . . rest on different factual allegations and distinct legal concepts."); *Marshall v. Sheldahl, Inc.*, 150 F. Supp. 2d 400, 403 (N.D.N.Y. 2001) (plaintiffs cannot prove defect and alternative design "by simply averring that the product would have been safe had it contained adequate warnings"). If the rule were otherwise, plaintiffs could always avoid the alternative-design requirement simply by proposing new warnings.

[11] Plaintiffs have already: (1) sought leave to move for reconsideration of Magistrate Judge Noel's order, which was denied (ECF No. 282); and (2) appealed to the District Court, which affirmed the order (ECF No. 304). To the extent Plaintiffs now seek reconsideration *for a second time*, Plaintiffs ignore the steps required by L.R. 7.1(j).

As to the remaining proposed alternatives, Dr. David relied on marketing brochures and 510(k) summaries to *speculate* they were safer, but offers no data or support for this assertion, and concedes he has none. (Ex. 11, David Dep. at 282:18-283:6.) And while Plaintiffs attempt to discredit the Cleveland Clinic study cited in Defendants' opening brief—arguing it fails to *disprove* the Bair Hugger System can feasibly be made safer—this argument is flawed because, among other reasons, it shifts the burden of proof. It is not Defendants' burden to *disprove* Plaintiffs' feasible safer alternative designs proposals; it is Plaintiffs' burden to prove their proposals are safer and can be incorporated into the Bair Hugger System without impacting its function. *Wagner v. Hesston Corp.*, 450 F.3d 756, 760 (8th Cir. 2006). Plaintiffs have made no such showing.

CONCLUSION

The Court should exclude Dr. David's opinions in their entirety.

Dated: October 17, 2017

Respectfully submitted,

s/Bridget M. Ahmann

Bridget M. Ahmann
MN Atty ID No. 016611x
M. Joseph Winebrenner
MN Atty ID No. 0387889
Attorneys for Defendants 3M Company and Arizant Healthcare Inc.
FAEGRE BAKER DANIELS LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402
T: (612) 766-7000 F: (612) 766-1600
bridget.ahmann@faegrebd.com
joe.winebrenner@faegrebd.com

Jerry W. Blackwell
MN Atty ID No. 0186867
Benjamin W. Hulse
MN Atty ID No. 0390952
Mary S. Young
MN Atty ID No. 0392781
Attorneys for Defendants 3M Company and Arizant Healthcare Inc.
BLACKWELL BURKE P.A.
431 South Seventh Street, Suite 2500
Minneapolis, MN 55415
T: (612) 343-3200 F: (612) 343-3205
blackwell@blackwellburke.com
bhulse@blackwellburke.com
myoung@blackwellburke.com

US.114499826